

**REMARKS**

After entry of this amendment, claims 1-54 and 56-78 will be pending for the Examiner's review and consideration. The Office Action dated October 16, 2003 has been carefully considered. Claims 1-5, 7, 8-19, 21-24, 25, 27-38, 40, 41, 43, 44, 46, 52, 56, 62, 70, 71, and 77 have been amended without prejudice to clarify the language used to describe the present inventions. Thus, no estoppel effect should be given to the amended claims. No new matter has been added. Reconsideration and allowance of the present application in view of the above amendments and the following remarks is respectfully requested.

In the Office Action dated October 16, 2003, the Examiner:

- rejected claims 1-2, 5-11, 14-15, 17-22, 25-30, 33-39, and 77-78 under 35 U.S.C. § 102(a) as being anticipated by United States Patent No. 5,899,939 to Boyce ("Boyce");
- rejected claims 56-57, 60, 62-66, 69-70, and 74-76 under 35 U.S.C. § 102(a) as being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as being unpatentable in view Boyce;
- rejected claims 12-13, 31-32, 58-59, 67-68, and 72-73 under 35 U.S.C. § 103(a) as being unpatentable over Boyce; and
- rejected claims 3-4, 16, 23-24, 35, 40-54, 61, and 71 under 35 U.S.C. § 103(a) as being unpatentable over Boyce in view of United States Patent No. 4,950,296 to McIntyre ("McIntyre").

**Independent Claim 1**

Independent claim 1 was rejected under 35 U.S.C. § 102(a) as being anticipated by Boyce. Independent claim 1 has been clarified to recite an implant comprising a body having an inner member and at least one outer member, each member being formed from a bone from a different region in the body and being formed with an exterior surface and an opening defining an interior surface, wherein the exterior surface of each inner member contacts the interior surface of no more than one other outer member, wherein the inner and outer members have a shape resembling at least a portion of a tubular member. There is no disclosure, teaching, or suggestion in Boyce of an implant comprising a body having an inner member and at least one outer member each member being formed with an exterior surface and an opening defining an interior surface, wherein the exterior surface of each inner

member contacts the interior surface of no more than one other outer member, wherein the inner and outer members have a shape resembling at least a portion of a tubular member.

Rather, Boyce discloses taking a long bone and slicing it longitudinally to form bone layers, the layers then being superimposed one on top of the other in an edge-to-edge fashion in a manner "analogous to planking." The implant may thereafter be machined into any desirable size and shape. Thus, Boyce does not disclose, teach, or suggest an implant comprising an inner member and at least one outer member wherein the inner and outer members have a shape resembling at least a portion of a tubular member and wherein the exterior surface of each inner member contacts the interior surface of no more than one other outer member.

Moreover, there is no disclosure, teaching, or suggestion in Boyce of an implant comprising a body having an inner member and at least one outer member, each member being formed from a bone from a different region in the body. Rather, Boyce discloses slicing a bone longitudinally to form bone layers, the layers being superimposed on top of the other wherein alternating layers are composed of fully mineralized cortical bone and partially demineralized cortical bone. Although, Boyce states that one or more layers could be made from a material other than the partially demineralized bone, Boyce does not disclose, teach, or suggest a body having an inner member and at least one outer member, each member being formed from a bone from a different region in the body.

Therefore, it is respectfully submitted that Boyce does not disclose, teach, or suggest all of the elements of independent claim 1. Thus, it is respectfully submitted that independent claim 1 is allowable over the cited prior art. Withdrawal of this rejection and allowance of independent claim 1 is respectfully requested.

Claims 2-20 all ultimately depend from independent claim 1, and thus, it is respectfully submitted that these claims are equally allowable. Withdrawal of these rejections and allowance of claims 2-20 is therefore respectfully requested.

#### **Independent Claim 21**

Independent claim 21 was rejected under 35 U.S.C. § 102(a) as being anticipated by Boyce. Independent claim 21 has been clarified to recite an implant comprising a body formed from a cross-section of a core and a plurality of substantially tubular members with each member having an inner surface and an outer surface, wherein at least two members are formed from bones from different regions of the body, the outer surface of a first member has

about the same contour as the inner surface of a second member so that the first and second members mate together, and the cross-section includes at least a portion of each member and core. There is no disclosure, teaching, or suggestion in Boyce of an implant comprising a body formed from a plurality of substantially tubular members with each member having an inner surface and an outer surface, the outer surface of a first member has about the same contour as the inner surface of a second member so that the first and second members mate together.

Rather, as previously stated, Boyce discloses taking a long bone and slicing it longitudinally to form bone layers, the layers then being superimposed one on top of the other in an edge-to-edge fashion in a manner "analogous to planking." The implant may thereafter be machined into any desirable size and shape. Thus, Boyce does not disclose, teach, or suggest an implant comprising a plurality of substantially tubular members with each member having an inner surface and an outer surface, the outer surface of a first member has about the same contour as the inner surface of a second member so that the first and second members mate together.

Moreover, there is no disclosure, teaching, or suggestion in Boyce of an implant comprising a plurality of substantially tubular members wherein at least two members are formed from bones from different regions of the body. Rather, as previously described, Boyce discloses slicing a bone longitudinally to form bone layers, the layers being superimposed on top of the other wherein alternating layers are composed of fully mineralized cortical bone and partially demineralized cortical bone. Although, Boyce states that one or more layers could be made from a material other than the partially demineralized bone, Boyce does not disclose, teach, or suggest an implant comprising a plurality of substantially tubular members wherein at least two members are formed from bones from different regions of the body.

Therefore, it is respectfully submitted that Boyce does not disclose, teach, or suggest all of the elements of independent claim 21. Thus, it is respectfully submitted that independent claim 21 is allowable over the cited prior art. Withdrawal of this rejection and allowance of independent claim 21 is respectfully requested.

Claims 22-39 all ultimately depend from independent claim 21, and thus, it is respectfully submitted that these claims are equally allowable. Withdrawal of these rejections and allowance of claims 22-39 is therefore respectfully requested.

**Independent Claim 40**

Independent claim 40 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Boyce in view of McIntyre. Independent claim 40 has been clarified to recite an implant comprising a plurality of members having a shape substantially resembling a portion of a tubular member each defining a hole, and a core sized and configured to fit within the innermost of the members, wherein the members are formed from at least two different bones selected from the group comprising a femur, tibia, humerus, fibula, ulna, and radius. There is no disclosure, teaching, or suggestion in Boyce of an implant comprising a plurality of members having a shape substantially resembling a portion of a tubular member each defining a hole, and a core sized and configured to fit within the innermost of the members. Rather, as previously stated, Boyce discloses taking a long bone and slicing it longitudinally to form bone layers, the layers then being superimposed one on top of the other in an edge-to-edge fashion in a manner "analogous to planking." The implant may thereafter be machined into any desirable size and shape. Thus, Boyce does not disclose, teach, or suggest an implant comprising a plurality of members having a shape substantially resembling a portion of a tubular member each defining a hole, and a core sized and configured to fit within the innermost of the members.

Moreover, there is no disclosure, teaching, or suggestion in Boyce of an implant comprising a plurality of members wherein the members are formed from at least two different bones selected from the group comprising a femur, tibia, humerus, fibula, ulna, and radius. Rather, as previously described, Boyce discloses slicing a bone longitudinally to form bone layers, the layers being superimposed on top of the other wherein alternating layers are composed of fully mineralized cortical bone and partially demineralized cortical bone. Although, Boyce states that one or more layers could be made from a material other than the partially demineralized bone, Boyce does not disclose, teach, or suggest an implant comprising a plurality of members wherein the members are formed from at least two different bones selected from the group comprising a femur, tibia, humerus, fibula, ulna, and radius.

Furthermore, McIntyre, either alone or in combination, does not rectify the failings of Boyce as McIntyre only discloses the ability to acquire bone for an implant from different regions in the body. McIntyre does not teach, disclose, or suggest forming an implant from

the combination of bone acquired from one region in the body with a bone acquired from a different region in the body.

Therefore, it is respectfully submitted neither Boyce or McIntyre, either alone or in combination, disclose, teach, or suggest all of the elements of independent claim 40. Thus, it is respectfully submitted that independent claim 40 is allowable over the cited prior art. Withdrawal of this rejection and allowance of independent claim 40 is respectfully requested.

#### **Independent Claim 41**

Independent claim 41 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Boyce in view of McIntyre. Independent claim 41 recites an implant comprising at least two layers of bone components coupled to each other, the components together defining at least one securing region, and at least one insertable securing element adapted for placement in the at least one securing region, wherein the implant is formed from at least two different bones selected from the group comprising a femur, tibia, humerus, fibula, ulna, and radius. There is no disclosure, teaching, or suggestion in Boyce of an implant comprising at least two layers of bone components coupled to each other, wherein the implant is formed from at least two different bones selected from the group comprising a femur, tibia, humerus, fibula, ulna, and radius.

Rather, as previously described, Boyce discloses taking a long bone and slicing it longitudinally to form bone layers, the layers then being superimposed one on top of the other in an edge-to-edge fashion in a manner "analogous to planking." The layers comprising alternating layers of fully mineralized cortical bone and partially demineralized cortical bone. Although, Boyce states that one or more layers could be made from a material other than the partially demineralized bone, Boyce does not disclose, teach, or suggest an implant comprising at least two layers of bone components coupled to each other, wherein the implant is formed from at least two different bones selected from the group comprising a femur, tibia, humerus, fibula, ulna, and radius.

Furthermore, McIntyre, either alone or in combination, does not rectify the failings of Boyce as McIntyre only discloses, as previously stated, the ability to acquire bone for an implant from different regions in the body. McIntyre does not teach, disclose, or suggest forming an implant from the combination of bone acquired from one region in the body with a bone acquired from a different region in the body.

Therefore, it is respectfully submitted neither Boyce or McIntyre, either alone or in combination, disclose, teach, or suggest all of the elements of independent claim 41. Thus, it is respectfully submitted that independent claim 41 is allowable over the cited prior art. Withdrawal of this rejection and allowance of independent claim 41 is respectfully requested.

Claims 42-54 all ultimately depend from independent claim 41, and thus, it is respectfully submitted that these claims are equally allowable. Withdrawal of these rejections and allowance of claims 42-54 is therefore respectfully requested.

#### **Independent Claim 56**

Independent claim 56 was rejected under 35 U.S.C. § 102(a) as being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as being unpatentable in view Boyce. Independent claim 56 has been clarified to recite an implant comprising a body having two outer annular members and at least one inner annular member, wherein at least one of the outer and inner annular members is formed from bone and the outer annular members are coupled together to define a central opening for receiving the at least one inner member. There is no disclosure, teaching, or suggestion in Boyce of an implant comprising a body having two outer annular members and at least one inner annular member, wherein the outer annular members are coupled together to define a central opening for receiving the at least one inner member.

Rather, as previously stated, Boyce discloses taking a long bone and slicing it longitudinally to form bone layers, the layers then being superimposed one on top of the other in an edge-to-edge fashion in a manner "analogous to planking." The implant may thereafter be machined into any desirable size and shape. Thus, Boyce does not disclose, teach, or suggest an implant comprising two outer annular members and at least one inner annular member, wherein the outer annular members are coupled together to define a central opening for receiving the at least one inner member.

Therefore, it is respectfully submitted that Boyce does not disclose, teach, or suggest all of the elements of independent claim 56. Thus, it is respectfully submitted that independent claim 56 is allowable over the cited prior art. Withdrawal of this rejection and allowance of independent claim 56 is respectfully requested.

Claims 57-76 all ultimately depend from independent claim 56, and thus, it is respectfully submitted that these claims are equally allowable. Withdrawal of these rejections and allowance of claims 57-76 is therefore respectfully requested.

**Independent Claim 77**

Independent claim 77 was rejected under 35 U.S.C. § 102(a) as being anticipated by Boyce. Independent claim 77 has been amended to recite an implant comprising a body having at least two ring-shaped members formed from bone, wherein the innermost ring-shaped member has an outer diameter, the outermost ring-shaped member has an inner diameter, the inner diameter is larger than the outer diameter so that the innermost ring-shaped member is received within the outermost ring-shaped member. There is no disclosure, teaching, or suggestion in Boyce of an implant comprising a body having at least two ring-shaped members formed from bone, wherein the innermost ring-shaped member has an outer diameter, the outermost ring-shaped member has an inner diameter, the inner diameter is larger than the outer diameter so that the innermost ring-shaped member is received within the outermost ring-shaped member.

Rather, Boyce discloses taking a long bone and slicing it longitudinally to form bone layers, the layers then being superimposed one on top of the other in an edge-to-edge fashion in a manner "analogous to planking." The implant may thereafter be machined into any desirable size and shape. Thus, Boyce does not disclose, teach, or suggest an implant comprising an innermost ring-shaped member having an outer diameter, an outermost ring-shaped member having an inner diameter, the inner diameter is larger than the outer diameter so that the innermost ring-shaped member is received within the outermost ring-shaped member.

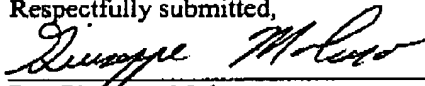
Therefore, it is respectfully submitted that Boyce does not disclose, teach, or suggest all of the elements of independent claim 77. Thus, it is respectfully submitted that independent claim 77 is allowable over the cited prior art. Withdrawal of this rejection and allowance of independent claim 77 is respectfully requested.

Claim 78 depends from independent claim 77, and thus, it is respectfully submitted that claim 78 is equally allowable. Withdrawal of this rejection and allowance of claim 78 is therefore respectfully requested.

In light of the above amendments and remarks, it is respectfully submitted that claims 1-53 and 55-78 are now in condition for allowance, and the Examiner is respectfully requested to reconsider this application with a view towards allowance. The Examiner is invited to call the undersigned attorney at 212-790-6348, if a telephone call could help resolve any remaining issues.

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Respectfully submitted,



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